5 510(k) Summary

K062793

Summary as required by section 807.92(c)

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Trade Names
Servo-i ventilator with NAVA option article no.; 66 71 957
Preparation date 2006-09-17

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Ventilator, continuous (Respirator)	73 CBK	II	21 CFR 868.5895

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Galileo Gold Hamilton w ASV option	K061090
Puritan Bennett w PAV+ option	K053388
Dräger EVITA XL w Smart Care	K051263
Servo-i ventilator family	K040221
Avea with Bicore option	K013642

Respitrace	K942852
Bicore	K935788
Sechrist Savi	K920121
Infant Star	K923704
Arzco esophagus electrodes (bi-polar)	K903136
Arzco esophagus electrodes (8 electrodes)	K905831
Vygon Gastric Feeding tube – for function	K925854
Utah medical (Gesco) Umbilical catheter – for material	K940870

Device Description
Summary of technological characteristics of modified Device and Predicate Device:
The predicate device Servo-i is a ventilator, which gives, ventilation (Invasive and Non Invasive) to critical care patients in the weight range 0.5 to 250 Kg's
The modified device is an option, called NAVA option (Neurally Adjusted Ventilatory Assist) which is a HW module with SW for Servo-i integration, which are added to the predicate device.

The Nava option uses an amplifier which in conjunction with a nasogastric feeding tube with microelectrodes detects signals to the diaphragm (Edi). The Edi is used as an additional detector to improve the synchrony between the patient and the ventilator and to give the patient corresponding ventilatory support.

Intended Use of the Device:
The intended use with the NAVA option is identical to the cleared Servo-i ventilator (K040221). The patient ranges are also the same.
The added indications for use of the NAVA option is that the electrical signal from the brain to the diaphragm is intact, and no contraindication for insertion/exchange of NG-tube

Comparison to predicate devices.
The activity of the diaphragm can be measured with changes in air flow/pressure at the mouthpiece or closer to origin by the pressure in esophagus, impedance changes of the thorax or through the electrical signal to the diaphragm (Edi). Predicate devices are using the mentioned physiologic phenomena to improve synchrony either through direct measurements or by using calculations of ventilatory related parameters detected at the mouthpiece. All methods have the same goal to improve synchrony and detection of the patient's need and/ or to simplify the weaning.

The predicate devices Puritan Bennett. PAV+ (K053388) , Hamilton GALILEO Gold ASV (K061090) and Dräger Evita XL with SmartCare (K051263) regulates the pressure related to patient efforts.

The predicate device Bicore (K935788) measures the esophageal pressure with a nasogastric tube or an esophageal tube. The trigger signal (Trig Detector) is used to improve synchrony (today in the Avea K013642).

Sechrist SAVI (K920121) uses impedance changes in thorax to improve the synchrony based on the same physiology.

Detection of the electrical activity to the diaphragm is substantial equivalent to monitoring system, which can be used to detect electro physiological signals from the esophagus as well as normal nasogastric feeding tubes.
Examples are Arzco electrodes for esophagus recording of the p-wave of the electrocardiogram as K903136 (bipolar) and K905831 (octa electrode catheter).
The polyurethane material are substantially equivalent to Umbilical catheters and venous catheter PICC-NATE (K940870, Gesco-Utahmedical).

Additional SE determination claims
The Servo-i ventilator with NAVA option meets the IEC 60601-2-12 standard for critical care ventilators.
Clinical and non clinical data is submitted to verify that the safe performance is substantial equivalent to the Servo-i ventilator with NAVA option.

The combination of known technology, physiological and medical knowledge and the information above together with a risk analysis comes to the conclusion that the NAVA option connected to a cleared Servo-i ventilator will give equal or more efficient ventilation and be as safe as the predicate Servo-i ventilator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Maquet Critical Care AB
C/O Mr. Jamie Yieh
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FEB 7 2007

Re: K062793
Trade/Device Name: Servo-i Ventilator with NAVA Option
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 26, 2007
Received: January 26, 2007

Dear Mr. Yieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K062796

Device Name: Servo-i ventilator with NAVA option

Indications For Use:

The Servo-i ventilator with NAVA option is intended for treatment and monitoring to improve synchrony between the ventilator and patients. The Servo-i with NAVA option is suitable for patient ranges of neonates, infants and adults with respiratory failure or respiratory insufficiency. Servo-i is a ventilator system to be used only by healthcare providers in hospitals or healthcare facilities and for in-hospital transport.
The added indications for use of the NAVA option is when the electrical signal from the brain to the diaphragm is intact; NAVA will improve synchrony between the ventilator and patients with no contraindication for insertion/exchange of a Naso Gastric tube.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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